

**Translation**

**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>33410026WO CSI/JLG</b>	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. <b>PCT/EP2004/007890</b>	International filing date (day/month/year) <b>15.07.2004</b>	Priority date (day/month/year) <b>15.07.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>C12N5/06, C07K14/47, A61K38/00, A61K39/00, C12N5/08</b>		
Applicant <b>PROTAGEN AG</b>		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>5</u> sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This report is based on translations from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of:
    - ☐ international search (Rule 12.3 and 23.1(b))
    - ☐ publication of the international application (Rule 12.4)
    - ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
  - ☐ the international application as originally filed/furnished
  - ☒ the description:
    - pages 1-49 \_\_\_\_\_ as originally filed/furnished
    - pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
    - pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
  - ☒ the claims:
    - nos. \_\_\_\_\_ as originally filed/furnished
    - nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19
    - nos.\* 1-26 received by this Authority on 26.08.2005 with letter of 25.08.2005
    - nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
  - ☒ the drawings:
    - sheets 1/10-10/10 \_\_\_\_\_ as originally filed/furnished
    - sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
    - sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
  - ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
  - ☐ the description, pages \_\_\_\_\_
  - ☐ the claims, nos. \_\_\_\_\_
  - ☐ the drawings, sheets/figs \_\_\_\_\_
  - ☐ the sequence listing (specify): \_\_\_\_\_
  - ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - ☐ the description, pages \_\_\_\_\_
  - ☐ the claims, nos. \_\_\_\_\_
  - ☐ the drawings, sheets/figs \_\_\_\_\_
  - ☐ the sequence listing (specify): \_\_\_\_\_
  - ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

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## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 12-20, 24-26 (in part)

because:

- ☐ the said international application, or the said claims Nos. \_\_\_\_\_  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 12-20, 24-26 (in part)

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

- |                            |  |
|----------------------------|--|
| the written form           | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☒ See Supplemental Box for further details.

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>1-26</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-26</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-26</u>	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
0. The amended claims do not go beyond the disclosure of the application as originally filed (PCT Article 34(2)(b)).			
1. Reference is made to the following documents:			
D2: PICCIRILLO C A ET AL, J. IM			
D10: WO 98/15624 A, 1998.			
2. The present application discloses that not all CD4+/CD25+ T cells, known <i>per se</i> from D2, express galectin-10. Claim 1 can be consequently be considered novel (PCT Article 33(2)); the same applies to the remaining claims.			
3. Claim 1 involves an inventive step (PCT Article 33(3)). D2 is considered to be the closest prior art. Said document differs from claim 1 in that the CD4+/CD25+ regulatory T cells in claim 1 contain galectin-10. The objective technical problem was, therefore, that of providing alternative CD4+/CD25+ T cells. In the absence of an unexpected technical effect, the			
/...			

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

CD4+/CD25+ T cells containing galectin-10 according to claim 1 would constitute, at best, an arbitrary selection from a number of possible solutions. However, examples 18 and 19 provide evidence of an unexpected technical effect of CD4+/CD25+ cells containing galectin-10 of the SEQ ID Nos: 1 or 2. In consequence, all the current claims involve an inventive step (PCT Article 33(3)). However, the applicant should refer also to Box VII below.

## Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

- 4.1 Claim 1 lacks clarity since "galectin-10" is not clearly delimited over other galectins. In consequence, the term "galectin-10" also encompasses the isoforms disclosed in claim 5, said isoforms not being structurally delimited (PCT Article 6). Moreover, the description (see page 6) states that galectin-10 according to D10 has only 60% sequence equivalence with SEQ ID Nos: 1 and 2. The applicant is advised that the inventive step in claim 1 is acknowledged on the basis of the unexpected technical effect of CD4+/CD25+ cells containing galectin-10 of SEQ ID Nos: 1 and 2, as disclosed in examples 18 and 19. There appears to be plausible support for this effect only in so far as said CD4+/CD25+ cells contain galectin-10 with sufficient structural similarity to SEQ ID No: 1 or. 2.
- 4.2 Claim 13 relates to "epitopes" in "binders" (thus, for example antibodies). However, for a person skilled in the art, the term "epitope" denotes antigenic determinants of antigens. Owing to the inconsistent use of the term, claim 13 lacks clarity (PCT Article 6).

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## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

## a. type of material



a sequence listing



table(s) related to the sequence listing

## b. format of material



in written format



in computer readable form

## c. time of filing/furnishing



contained in the international application as filed



filed together with the international application in computer readable form



furnished subsequently to this Authority for the purposes of search and/or examination

received by this Authority as an amendment\* on 18.11.2004

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

The sequence listing in the description, pages 1-42, as originally filed.

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

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## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

**Box III**

The current claims 12-20 and 24-26 relate to a disproportionately large number of potential "binders". The search was directed to the parts of the claims that, relate to antibodies. Accordingly, with regard to the aforementioned claims, the present report is restricted to antibodies, instead of "binders".